REMARKS

Claims 32-33, 36-37, 41-57, 74-75 and 77-78 are pending in the present application. Claims 32 and 77 have been amended and claim 78 has been added. Amendment to claim 32 further defines the metes and bounds of the claimed invention by adding the accession numbers of the Rpn11 and Rpn11 complex. New claim 78 is substantially similar to claim 32, but directed to AMSH polypeptides, as is amended claim 77. Hence, amendments to the claims are supported by the specification as well as by the original claims and no new matter has been added.

Applicants and Applicants' representatives gratefully acknowledge the careful consideration of the application and helpful suggestions regarding amendment of the claims made by Examiners Pak and Achutamurthy in the telephone interview held on October 31, 2005. It is submitted, that at the conclusion of the telephone interview, it was agreed that the finality of the rejection in the Office Action mailed September 8, 2005 would be withdrawn.

Additionally, Applicants and Applicants' representatives gratefully acknowledge that Examiner Pak via voicemail on November 8, 2005 will graciously consider and enter the following Amendment.

Applicants submit, that the amendments herein put the claims in condition for allowance, and such is respectfully requested.

I. Amendment to the claims

Claim 32 has been amended to recite the Accession numbers for Rpn11. Claim 32 has also been amended to delete AMSH polypeptides, which is the subject matter of new claim 78. Accession numbers for AMSH polypeptides are also provided. Claim 77 has been amended to depend on new claim 78.

Rpn11, Rpn11 complex and AMSH polypeptides are well known in the art. Amendment to claim 32 and new claim 78 further define the metes and bounds of the claimed invention by reciting the accession numbers of the Rpn11 and Rpn11 complex and AMSH, respectively. The Accession numbers are not considered new matter as discussed in further detail below.

Hence, amendments to the claims are supported by the specification as well as by the original claims and no new matter has been added.

II. Rejection under 35 U.S.C. § 112, first paragraph (written description rejection)

Claims 32-33, 36-37, 41-57, 74-75 and 77 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to convey to one skilled in the art that the inventors, at the time the application was filed, were in possession of the claimed invention. Applicants respectfully traverse this rejection as it applies to the amended claims.

According to the Office Action, the claimed invention is allegedly drawn broadly to methods of identifying agents affecting the isopeptidase activity of Rpn11, Rpn11 complex or AMSH. The Office Action states that although Rpn11, Rpn11 and AMSH polypeptides containing JAMM domains (SEQ ID NO:1), the claimed invention remains insufficient because it allegedly describes a "genus" of Rpn11, Rpn11 and AMSH polypeptides having JAMM domains. That is, according to the Office Action, the claimed invention allegedly encompasses *any* recombinants, variants and mutants of Rpn11, Rpn11 and AMSH polypeptides having JAMM domains for identifying *any* modifier or target proteins (page 4-5 of the Office Action).

Claim 32 has been amended and new claim 78 recite the accession numbers of the claimed polypeptides. According to *Capon v. Eshhar*, 76 USPQ2d 1078 (CA FC 2005), the amendment to the claims do not add new matter. In *Capon*, the Board erred when it objected to the claims being allegedly broader than the specific examples in the specification. Also, according to the Board, "controlling precedent" (*Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 [43 USPQ2d 1398] (Fed. Cir. 1997); *Fiers v. Revel Co.*, 984 F.2d 1164 [25 USPQ2d 1601] (Fed. Cir. 1993); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 [18 USPQ2d 1016] (Fed. Cir. 1991); and *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316 [63 USPQ2d 1609] (Fed. Cir. 2002)) requires inclusion in the specification of the complete nucleotide sequence of "at least one" [chimeric] gene. *Capon,* at 1083. Further, according to the Board, statutory requirements of 35 U.S.C. §112, first paragraph, requires that the specification must reproduce the "structure, formula, chemical name, or physical properties" of the claimed DNA combinations.

Both parties in *Capon* argued that persons having ordinary skill in the art would not have been able to visualize and recognize the identity of the claimed genetic material without considering additional knowledge in the art, performing additional experimentation, and testing to confirm results. That is, the statutory requirement of the "structure, formula, chemical name, or physical properties" of the claimed DNA combinations had been overtaken by the state of the science. The parties stated that where the structure and properties of the DNA components were known, reanalysis was *not* required. *Capon,* at 1083. In short, both parties argued that precedent cases did not establish a *per se* rule requiring nucleotide-by-nucleotide re-analysis when the structure of the component DNA segments was already known, or readily determined by known procedures. *Capon*, at 1083.

In *Capon,* the CAFC agreed with both parties in that the Board erred in refusing to consider the state of the scientific knowledge, because none of the cases to which the Board attributes the requirement of total DNA re-analysis, *i.e.*, *Regents v. Lilly, Fiers v. Revel, Amgen,* or *Enzo Biochem*, required a re-description of what was already known. *Capon,* at 1084. In

brief, the CAFC stated that, when the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh. *Capon,* at 1085.

Thus, based on the foregoing, Applicants submit that the *per se* description of Rpn11, Rpn11 complex and AMSH polypeptides in the specification/description is not required in as much as the information was already available to one skilled in the art. However, to advance the prosecution of the claimed invention, claims 32 and new claim 78 have included the recitation of the Rpn11, Rpn11 complex and AMSH polypeptides. Thus, based on the foregoing, the claimed invention is sufficiently described (e.g., Examples 1-3) in the specification because the nucleotide sequences encoding Rpn11, Rpn11 complex and AMSH polypeptides were well known in the art at the time of the filing of the above application. Therefore, at the time the application was filed, Applicants were in possession of the claimed invention.

Accordingly, withdrawal of the rejection of claims under 35 U.S.C. § 112, first paragraph (written description) is respectfully requested.

III. Rejection under 35 U.S.C. § 112, first paragraph (enablement)

Claims 32-33, 36-37, 41-57, 74-75 and 77 are rejected under 35 U.S.C. § 112, first paragraph for allegedly not providing enablement for a method of using *any* Rpn11, Rpn11 complex or AMSH having any structure. Applicants respectfully traverse this rejection as it applies to the amended claims.

According to the Office Action, the specification does not allegedly enable one skilled in the art to make and use the invention commensurate in scope with the claims without undue experimentation (page 6 of the Office Action). Further, according to the Office Action, although the claims are limited to polypeptide structures of Rpn11, Rpn11 complex and AMSH having the JAMM domain as set forth in SEQ ID NO:1, the claims allegedly encompass *any* Rpn11, Rpn11 complex and AMSH that cleaves *any/all* modifier proteins and/or target proteins (page 6 of the Office Action).

Applicants submit that the specification sufficiently enables one skilled in the art to which it pertains to make and use the claimed invention. As discussed above, Applicants submit that the recitation of the accession numbers is not necessary as indicated in *Capon v. Eshhar*, 76 USPQ2d 1078 (CA FC 2005), because the prior art includes the nucleotide information, and there is no *per se* rule that the information must be determined afresh. However, in order to advance the above application, claims 32 and new claim 78 recite the accession numbers for Rpn11, Rpn11 complex and AMSH polypeptides used in the screening methods. Thus, Applicants have provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims.

Accordingly, withdrawal of the rejection of the claims under 35 U.S.C. § 112, first paragraph (enablement) is respectfully requested.

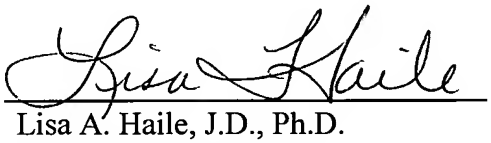
Conclusion

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

No fee is deemed to be due in connection with this response. However, if any additional fee is due, the Commissioner is hereby authorized to charge any other fees associated with the filing submitted herewith, or credit any overpayments to Deposit Account No. 07-1896. A copy of the Transmittal Sheet is enclosed.

Respectfully submitted,

Date: December 2, 2005



Lisa A. Haile, J.D., Ph.D.
Registration No. 38,347
Telephone: (858) 677-1456
Facsimile: (858) 677-1465

DLA PIPER RUDNICK GRAY CARY US LLP
4365 Executive Drive, Suite 1100
San Diego, California 92121-2133
USPTO Customer No. 28213